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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,046	12/05/2003	Alexander M. Harmon	022956-0235	9312
21125 7590 10/02/2008 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604				
EXAMINER				
STEWART, ALVIN J				
ART UNIT		PAPER NUMBER		
3774				
NOTIFICATION DATE		DELIVERY MODE		
10/02/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doctet@nutter.com

### Office Action Summary

**Application No.**

10/729,046

**Applicant(s)**

HARMON ET AL.

**Examiner**

Alvin J. Stewart

**Art Unit**

3774

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7, 9, 10, 12-25, 27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) 7, 14-19, 21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9, 10, 12, 13, 20, 23-25, 27 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/05/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Final Drawing Review (PTO-848)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8/27/08
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments filed 8/27/08 have been fully considered but they are not persuasive.

The Applicant's representative discloses that the Badylak et al reference does not disclose at least one minced tissue fragment containing a plurality of viable cells and the tissue fragment is associated with the isolated biological tissue slice.

The Examiner completely disagrees with the Applicant's representative point of view. For example, it is well established from the previous office actions that the Badylak et al reference clearly discloses a biological tissue that is at least minced to create a structure and is capable of containing a plurality of viable cells that can migrate from the implant.

The Applicant's representative added at least one minced tissue fragment to the existing claims in order to overcome the previous rejection but the Applicant's representative used the word "associated" when relating the minced tissue fragment with the isolated biological tissue slice.

The Examiner interpreted the word "associated" as follow: ---to joint or to keep company with---. Therefore, the minced tissue fragment can be part of the tissue slice. For example, the Examiner can interpret the whole implant (the whole SIS tissue) as the tissue slice, then the Examiner can interpret a section (a fragment) of the whole implant as the minced tissue fragment. Therefore, the tissue fragment is associated with the tissue slice.

Second, the Examiner can also interpreted the claims as follow: Badylak et al discloses in col. 2, lines 15-19; col. 5, lines 25-27; and col. 16, lines 29-34 disclosing an implant having a

plurality of layers, wherein one layer can be interpreted as the tissue slice and a second layer can be interpreted as the minced tissue fragment.

The Applicant's representative has to positively claim more structure limitations in order to at least describe the invention and try to distinguish the Applicant's invention with respect to the prior art. Especially, try to differentiate the tissue slice to the tissue fragment. Does the tissue fragment comprise a different layer than the tissue slice? Or they are the same? The use of the word "associate" make the claim so broad that makes very difficult to the Examiner to try to understand what the Applicant's representative is trying to claim.

***Claim Rejections - 35 USC § 103***

Claims 1-6, 9, 12-13, 20, 23-25 and 27-28 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Badylak et al US Patent 6,485,723.

Badylak et al discloses a biocompatible tissue implant comprising a naturally occurring biocompatible tissue slice having a geometry, the tissue slice including an effective amount of viable cells (see col. 2, lines 15-19; col. 3, lines 1-5; col. 3, lines 18-20; col. 3, lines 30-61; col. 4, lines 1-14) and further being dimensioned so that the cells can migrate out of the tissue disclosing the tissue strip and the sutures.

With respect to the new limitations, the Examiner can interpret the whole implant (the whole SIS tissue) as the tissue slice, then the Examiner can interpret a section (a fragment) of the whole implant as the minced tissue fragment. Therefore, the tissue fragment is associated with the tissue slice.

Additionally, the Badylak et al reference discloses in col. 2, lines 15-19; col. 5, lines 25-27; and col. 16, lines 29-34 an implant having a plurality of layers, wherein one layer can be interpreted as the tissue slice and a second layer can be interpreted as the minced tissue fragment. For the above reasons, the Examiner made also a 103(a) rejection because the embodiment of the plurality of tissues does not mention how those tissues are made.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the plurality of layers of SIS by a layer of SIS that is made of a mince, tear, cut or any other cutting step similar to the ones describes above (as disclosed in another embodiment shown in col. 4, lines 43-50).

Regarding the retaining element, see col. 24, lines 28-29.

Regarding claims 4-6, see col. 16, lines 38-53.

Regarding claim 23, see col. 5, lines 1-12.

NOTE: claim 10 has not been examined because claim 9 is referring to a Markush claim and the Examiner only select one element from the group. The elected group is a suture.

Regarding claim 13, Badylak et al discloses the claimed invention except for particles sizes having a range of about  $0.1 \text{ mm}^3$  to  $2 \text{ mm}^3$ . It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the particle size, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alvin J Stewart/  
Primary Examiner, Art Unit 3774

September 25, 2008.